delayed cerebral ischemia after subarachnoid ahemorrhage: an prospective observational study

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To further investigate the pathogenesis of DCI and its relation to gender, decreased fibrinolysis, increased coagulation, and hormonal factors in order to eventually pave the way for new treatment options.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system vascular disorders
Study type	Observational invasive

Summary

ID

NL-OMON39377

Source
ToetsingOnline

Brief title
DISCOVER

Condition

- Central nervous system vascular disorders

Synonym
brain haemorrhage, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: delayed cerebral ischemia, fibrinolysis, subarachnoid haemorrhage, vasospasm

Outcome measures

Primary outcome

The relationship of delayed cerebral ischemia occurence with blood coagulation parameters and sex hormones:

-ESR, Blood count, Glucose, Kreatinine, Calcium, Albumin, Magnesium, CRP

-D-dimer, Von Willebrand factor, ADAMTS13, Prothrombin fragment 1 and 2, Endogenious thrombin potential

-17-beta-estradiol, Progesterone, Testosterone, Dihydrotestosterone

Secondary outcome

1) To evaluate whether occurrence of DCI after SAH is gender-specific

2) To study imaging of patient with SAH in order to evaluate whether patients with and without DCI develop cerebral infarction.

3) To assess whether the glycocalyx is affected in SAH patients and is related to its severity and the development of DCI.

4) To evaluate whether glycocalyx perturbation is associated with vasomotion changes as non-invasively assessed by finger arterial waveform registration, in SAH patients.

Study description

Background summary

Delayed cerebral ischemia (DCI) is a complication of subarachnoid haemorrhage (SAH), a devastating form of stroke mostly affecting young adults. The pathogenesis of DCI is still not well understood, making treatment options difficult. While it was thought before that it was caused by vasospasm of the cerebral vasculature, more recent studies have shown a role for microthrombus formation by decreased fibrinolysis, an increase in coagulation and changes in endothelial function. Moreover recent work has revealed that treatment of DCI after SAH to only be effective in female patients, suggesting a role for gender in the pathogenesis of DCI.

Study objective

To further investigate the pathogenesis of DCI and its relation to gender, decreased fibrinolysis, increased coagulation, and hormonal factors in order to eventually pave the way for new treatment options.

Study design

prospective observational cohort study

Study burden and risks

Patients will undergo blood sampling at baseline and at 6 fixed time points during hospital stay. Each time 30 mlof blood will be drawn. We will make use of existing catheters and lines for drawing of blood. When needed blood will be collected by venous puncture, which has been shown to be safe. We expect the risk to the patient from the sampling of blood to be negligible. Additionally in a subgroup of 40 patients the peripheral and central hemodynamics will be assessed using continuous finger arterial pressure (FinAp) waveform registration by Nexfin. These patients will additionally be asked to give consent to a glycocalyx volume m,easurement with Sideview Dark Field (SDF) imaging (a camera under the tonque). Both of these measuring thechniques are not harmfull to the patient. We will also have to include incapacitated patients, because most patients with SAH are acutely ill and will not be able to give consent themselves. It would not be possible to investigate this disease without bias if we were to exclude incapacitated patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with suspected aneurysmal subrarachnoid haemorrhage

Exclusion criteria

1) Under 18 years of age
2) Presentation >72 hours after initial ictus of haemorrhage
3) If death appears imminent

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-02-2013
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	31-08-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	22-03-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL39814.018.12